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Subject: Formaldehyde News

FYI-In case you had not seen this..

## EPA Stalls Formaldehyde Study, Despite Congress' Direction, Agency Pledge

July 02, 2018

EPA's reluctance to advance its latest draft assessment of the human health risks of formaldehyde, allegedly because political appointees have blocked its release, appears to be at odds with Congress' direction in the agency's 2017 budget for officials to send the study to peer review and the agency's subsequent commitment to do so by Sept. 30, 2018.

It may also be at odds with the agency's Scientific Integrity Policy, which seeks to protect agency science from political interference and generally bars personnel, including political appointees, from delaying release of scientific documents.

"We continue to discuss this assessment with our Agency program partners and have no further updates to provide at this time," an EPA spokeswoman said.

EPA's Integrated Risk Information System (IRIS) program has been working for years to complete its assessment of formaldehyde's risks, a document that is expected to renew a long-running and controversial debate on whether the substance poses not just nasal cancer risks but also more worrisome leukemia risks.

Once completed, the assessment will likely drive stricter regulatory requirements, including in air toxics rules for the wood products sector, which is pending, and for natural gas turbines.

An early draft that EPA released in the Obama administration identified possible leukemia risks, a finding that industry groups have strongly criticized, citing studies showing no biological mechanism by which formaldehyde could cause leukemia.

The early draft was also strongly criticized by a National Academy of Sciences (NAS) panel, which faulted IRIS' methodology in crafting its draft and warned of a pattern of problems in how such assessments are developed in the IRIS program, that have forced the program into years of reforms amid continuing criticisms from industry and GOP critics.

The latest draft IRIS assessment, seven years in the making, has yet to be released for public comment or peer review by the NAS -- despite signs from agency officials that it was expected to be released soon.

This prompted questions about its status from three Democratic senators last month, who alleged that political appointees were delaying release of the draft which shows that the substance causes leukemia and other types of cancer.

In <u>a May 17 letter</u> to Administrator Scott Pruitt, Sens. Tom Carper (DE), Ed Markey (MA) and Sheldon Whitehouse (RI) said they believe officials are delaying the latest draft because it found the substance to be "carcinogenic, presenting evidence for nasopharyngeal cancer and leukemia, among other risks to human health."

They said they have learned that the latest draft IRIS assessment of formaldehyde was completed "during the fall of 2017," but that the agency has yet to proceed through the regular intra-agency review process normally undertaken before a document is released for inter-agency review, public comment, and peer review.

The senators charge that "EPA by now should have published the assessment for public comment," but that it has not because "multiple political appointees within EPA have expressed reluctance to move the assessment through the agency review process, have repeatedly set up briefings on the assessment only to later cancel them, and/or have insisted that IRIS first set up briefings for industry stakeholders before completing agency review."

The senators named Pruitt's chief of staff, Ryan Jackson, air office chief Bill Wehrum and toxics office appointee Nancy Beck as among those delaying the formaldehyde assessment's public release.

The senators asked a series of questions and sought a response from EPA by June 6. It is not clear whether the agency has responded.

## **New NAS Contract**

The agency's failure to release the draft document comes despite a formal commitment to Congress that it will release the draft in fiscal year 2018, which ends Sept. 30.

In <u>a report to Congress</u> on IRIS last January, which provides details on the formaldehyde assessment, the agency noted that in the Consolidated Appropriations Act of 2017's accompanying explanatory language, "Congress requested actions related to . . . [peer] review for the draft IRIS assessment of formaldehyde," among other things.

EPA explains in the report that it has already "contracted the NAS to conduct the peer review of the revised draft IRIS assessment of formaldehyde. The draft report will go through the formal review process which will involve public comment before delivery to the NAS for peer review."

The agency said IRIS "plans to deliver an External Review Draft of its Formaldehyde Assessment for public comment and peer review in FY 2018."

The reported delay of the draft assessment also appears to violate EPA's Scientific Integrity Policy, <u>published in 2012</u> to protect agency science from political interference. The policy, still located on EPA's website, states that "[t]o support a culture of scientific integrity within the Agency, this policy ... Prohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions."

Tina Bahadori, the new chief of the center overseeing IRIS, told EPA's Science Advisory Board (SAB) at its last meeting June 1 that the program has learned from its experience with the formaldehyde assessment.

"Really, formaldehyde was where we learned this lesson," Bahadori said. "Had we thought about this approach, that really we do not need to reinvent everything in the IRIS program. That we could have, when you see the recommendations from [NAS], built that assessment, rather than build it from scratch like we did, take a good part of seven or eight years, and re-start the controversies around that assessment, had we worked from settled science and just worked on developing our systematic review approaches we wouldn't be in the quagmire that we are today around formaldehyde."

Bahadori added that starting the formaldehyde assessment over from the beginning, "what it did was it lost the confidence people had in our ability to produce the assessment in a timely way. We got caught up in our own controversy. We learned from that and we are working to not make that same mistake."

## Report To Congress

EPA in its report to Congress says that the IRIS program has implemented NAS' reform recommendations, both generally and specific to the formaldehyde assessment.

In particular, the report points to IRIS' efforts to adopt systematic review, an approach to searching and analyzing research intended to be more rigorous and transparent in hazard identification. EPA notes this recommendation was included in both NAS' critical 2011 formaldehyde assessment report, as well as a 2014 followup report on the overall IRIS program, which was generally supportive of EPA's efforts to address NAS' recommendations for IRIS.

EPA last publicly addressed the formaldehyde assessment four years ago, when the IRIS program hosted a workshop intended to help address the thorny scientific issues stalling the formaldehyde assessment.

Among those who attended the May 2014 meeting was Beck, who at the time represented the American Chemistry Council trade group.

According to an *Inside EPA* report from the meeting, Beck said she would "like to see an assessment completed in my lifetime" and pressed the speakers to discuss what EPA could do with the available formaldehyde data. -- *Maria Hegstad* (<a href="mailto:mhegstad@iwpnews.com">mhegstad@iwpnews.com</a>)

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